

<b>Form PTO/SB/08A2 (Modified)</b> <b>Information Disclosure Statement By Applicant</b> <i>(Use Several Sheets if Necessary)</i>	<b>Atty Docket No.:</b> 0005.16	<b>Application No.:</b> 10/613,078
<b>Applicant:</b> John S. Patton et al.		
<b>Filing Date:</b> 07/01/2003		<b>Group:</b> 1616

**U.S. Patent Documents**

Examiner Initial		Patent No.	Date	Patentee	Class	Sub-Class	Filing Date
<i>ku</i>	*	2,598,525	05/1952	Fox	—	—	
	*	3,202,731	08/1965	Grevenstuk et al.			
	*	3,300,474	01/1967	Flodin et al.			
	*	3,314,803	04/1967	Tarrytown et al.			
	*	3,362,405	01/1968	Hazel			
	*	3,425,600	02/1969	Ablanalp			
	*	3,540,927	11/1970	Niimi et al.			
	*	3,554,768	01/1971	Feldman			
	*	3,620,776	11/1971	Mishkin et al.			
	*	3,666,496	05/1972	Honey et al.			
	*	3,674,901	07/1972	Shepherd et al.			
	*	3,764,716	10/1973	Rainwater et al.			
	*	3,921,637	11/1975	Bennie et al.			
	*	3,937,668	02/1976	Zolle			
	*	3,964,483	06/1976	Mathes			
	*	3,971,852	07/1976	Brenner et al.			
	*	3,991,304	11/1976	Hillsman			
	*	3,991,761	11/1976	Cocozza			
	*	3,994,421	11/1976	Hansen			
	*	4,036,223	07/1977	Obert			
	*	4,069,819	01/1978	Valentini et al.			
	*	4,098,273	401/1978	Glenn			
	*	4,109,019	08/1978	Moore			
	*	4,153,689	05/1979	Hiral et al.			
	*	4,206,200	06/1980	Guthohrlein et al.			
	*	4,211,769	07/1980	Okada et al.			
	*	4,249,526	02/1981	Dean et al.			
	*	4,253,468	03/1981	Lehmbeck			
	*	4,294,624	10/1981	Veltman			
<i>ku</i>	*	4,294,829	10/1981	Suzuki et al.	—	—	

<b>Examiner:</b> <i>Ku</i>	<b>Date Considered:</b> <i>12/04</i>
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Examiner: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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**U.S. Patent Documents**

Examiner Initial		Patent No.	Date	Patentee	Class	Sub- Class	Filing Date
Lsu	*	4,338,931	07/1982	Cavazza	—	—	
	*	4,423,079	12/1983	Kline			
	*	4,446,862	05/1984	Baum et al.			
	*	4,452,239	06/1984	Malem			
	*	4,484,577	11/1984	Sackner et al.			
	*	4,503,035	03/1985	Pestka et al.			
	*	4,533,552	08/1985	Kawamata et al.			
	*	4,534,343	08/1985	Nowacki et al.			
	*	4,559,298	12/1985	Fahy			
	*	4,590,206	05/1986	Forrester et al.			
	*	4,599,311	07/1986	Kawasaki			
	*	4,614,730	09/1986	Hansen			
	*	4,617,272	10/1986	Kirkwood et al.			
	*	4,624,251	11/1986	Miller			
	*	4,627,432	12/1986	Newell et al.			
	*	4,649,911	03/1987	Knight et al.			
	*	4,659,696	04/1987	Hirai et al.			
	*	4,677,975	07/1987	Edgar et al.			
	*	4,698,328	10/1987	Neer et al.			
	*	4,729,754	04/1988	Shaner			
	*	4,778,054	10/1988	Newell et al.			
	*	4,790,305	12/1988	Zoltan et al.			
	*	4,806,343	02/1989	Carpenter et al.			
	*	4,807,814	02/1989	Douche et al.			
	*	4,811,731	03/1989	Newell et al.			
	*	4,819,629	04/1989	Jonson			
	*	4,820,534	04/1989	Saleeb et al.			
	*	4,823,784	04/1989	Borkoni et al.			
*	4,824,938	04/1989	Koyama et al.				
Lsu	*	4,830,858	05/1989	Payne et al.	—	—	

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**U.S. Patent Documents**

Examiner Initial		Patent No.	Date	Patentee	Class	Sub- Class	Filing Date
Lsu	*	4,833,125	05/1989	Neer et al.	—	—	
	*	4,855,157	08/1989	Tashiro et al.			
	*	4,857,319	08/1989	Crowe et al.			
	*	4,876,241	10/1989	Feldman et al.			
	*	4,884,565	12/1989	Cocozza			
	*	4,889,114	12/1989	Kladders			
	*	4,891,319	01/1990	Roser			
	*	4,895,719	01/1990	Radhakrishnan et al.			
	*	4,897,353	01/1990	Carpenter et al.			
	*	4,907,583	03/1990	Wetterlin et al.			
	*	4,919,962	04/1990	Arora et al.			
	*	4,926,852	05/1990	Zoltan et al.			
	*	4,927,763	05/1990	Sudoma et al.			
	*	4,931,361	06/1990	Baldeschwieler et al.			
	*	4,942,544	07/1990	McIntosh et al.			
	*	4,946,828	08/1990	Markussen			
	*	4,956,295	09/1990	Sudoma			
	*	4,968,607	11/1990	Dower et al.			
	*	4,984,158	01/1991	Hillsman			
	*	4,995,385	02/1991	Valentini et al.			
	*	5,011,678	04/1991	Wang et al.			
	*	5,017,372	05/1991	Hastings			
	*	5,026,566	06/1991	Foster			
	*	5,027,806	07/1991	Zoltan et al.			
	*	5,033,463	07/1991	Cocozza			
	*	5,035,237	07/1991	Newell et al.			
	*	5,042,975	08/1991	Chien et al.			
	*	5,048,514	09/1991	Ramella			
	*	5,049,388	09/1991	Kright et al.			
Lsu	*	5,081,228	01/1992	Dower et al.	—	—	

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**U.S. Patent Documents**

Examiner Initial		Patent No.	Date	Patentee	Class	Sub-Class	Filing Date
LSE	*	5,093,316	03/1992	Lezdey et al.	—	—	
	*	5,098,893	03/1992	Franks et al.			
	*	5,099,833	03/1992	Michaels			
	*	5,113,855	05/1992	Newhouse			
	*	5,124,162	06/1992	Boskovic et al.			
	*	5,139,016	08/1992	Waser			
	*	5,149,543	09/1992	Cohen et al.			
	*	5,149,653	09/1992	Roser			
	*	5,161,524	11/1992	Evans			
	*	5,180,812	01/1993	Dower et al.			
	*	5,186,164	02/1993	Raghuprasad			
	*	5,200,399	04/1993	Wettlaufer et al.			
	*	5,204,108	04/1993	Illum			
	*	5,206,200	04/1993	Bush et al.			
	*	5,230,884	07/1993	Evans et al.			
	*	5,253,468	10/1993	Raymond			
	*	5,254,330	10/1993	Ganderton			
	*	5,260,306	11/1993	Boardman et al.			
	*	5,290,765	03/1994	Wettlaufer et al.			
	*	5,295,479	03/1994	Lankinen			
	*	5,302,581	04/1994	Sarin et al.			
	*	5,309,900	05/1994	Knoch et al.			
	*	5,320,094	06/1994	Laube et al.			
	*	5,320,714	06/1994	Brendel			
	*	5,331,953	07/1994	Anderson et al.			
	*	5,354,562	10/1994	Platz			
	*	5,354,934	10/1994	Pitt et al.			
	*	5,356,635	10/1994	Raman et al.			
	*	5,364,838	11/1994	Rubsamen			
LSE	*	5,376,359	12/1994	Johnson	—	—	

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**U.S. Patent Documents**

Examiner Initial		Patent No.	Date	Patentee	Class	Sub- Class	Filing Date
LSH	*	5,384,133	01/1995	Boyes et al.	—	—	
	*	5,376,386	12/1994	Ganderton			
	*	5,419,315	05/1995	Rubsamen			
	*	5,447,151	09/1995	Bruna et al.			
	*	5,458,135	10/1995	Patton			
	*	5,482,927	01/1996	Maniar et al.			
	*	5,506,203	04/1996	Backstrom et al.			
	*	5,518,998	05/1996	Backstrom et al.			
	*	5,558,085	09/1996	Rubsamen et al.			
	*	5,619,984	04/1997	Hodson et al.			
	*	5,672,581	09/1997	Rubsamen et al.			
	*	5,755,221	05/1998	Bisgaard			
	*	5,997,848	12/1999	Patton et al.			
	*	6,012,454	01/2000	Hodson et al.			
	*	6,019,968	02/2000	Platz et al.			
	*	6,051,256	04/2000	Platz et al.			
	Lm	*	6,099,517	08/2000	Daugherty		
*		6,402,733	06/2002	Daugherty			
*		6,582,728	06/2003	Platz et al.			
*		6,685,967	02/2004	Patton et al.	—	—	


<b>Examiner:</b> <i>KLM</i>	<b>Date Considered:</b> <i>12/04</i>
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**Foreign Patent or Published Foreign Patent Application**

Examiner Initial	No.	Document No.	Publication Date	Country or Patent Office	Class	Sub- class	Translation Yes No				
HSE	*	902 257	08/1985	BE	—	—					
	*	18 12 574	06/1970	DE							
	*	24 15 159	10/1975	DE							
	*	31 41 498	04/1983	DE							
	*	01 61 072	09/1984	DE							
	*	0 015 123	09/1980	EP							
	*	0 072 046	02/1983	EP							
	*	0 111 216	06/1984	EP							
	*	0 122 036	10/1984	EP							
	*	0 140 489	05/1985	EP							
	*	0 193 372	09/1986	EP							
	*	0 229 810	07/1987	EP							
	*	0 237 507	09/1987	EP							
	*	0 289 336	11/1988	EP							
	*	0 302 772	02/1989	EP							
	*	0 347 779	12/1989	EP							
	*	0 360 340	03/1990	EP							
	*	0 364 235	04/1990	EP							
	*	0 366 303	05/1990	EP							
	*	0 383 569	08/1990	EP							
	*	0 468 914	01/1992	EP							
	*	0 467 172	01/1992	EP							
	*	0 490 797	06/1992	EP							
	*	0 506 293	09/1992	EP							
	*	0 611 567	08/1994	EP							
	*	0 655 237	05/1995	EP							
	*	8403520	02/1983	ES							
	*	2257351	01/1974	FR							
	*	1 288 094	09/1972	GB							
	HSE	*	1 477 775	06/1977			GB	—	—		

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**Foreign Patent or Published Foreign Patent Application**

Examiner Initial	No.	Document No.	Publication Date	Country or Patent Office	Class	Sub- class	Translation Yes No	
LSC	*	1 527 605	10/1978	GB				
	*	2 105 189	03/1983	GB				
	*	2 126 588	03/1984	GB				
	*	56138110	10/1981	JP				
	*	56138111	10/1981	JP				
	*	62267238	11/1987	JP				
	*	59095885	02/1984	JP				
	*	61293201	12/1986	JP				
	*	7712041	05/1979	NL				
	*	0628930	09/1978	RU				
	*	1003926	03/1983	RU				
	*	0883174	11/1981	RU				
	*	84/00294	02/1984	WO				
	*	86/04095	07/1986	WO				
	*	87/00196	01/1987	WO				
	*	87/05300	09/1987	WO				
	*	88/04556	06/1988	WO				
	*	88/09163	12/1988	WO				
	*	90/04962	05/1990	WO				
	*	90/05182	05/1990	WO				
	*	90/07351	07/1990	WO				
	*	90/09780	09/1990	WO				
	*	90/15635	12/1990	WO				
	*	91/02545	03/1991	WO				
	*	91/02558	03/1991	WO				
	*	91/06282	05/1991	WO				
	*	91/16038	10/1991	WO				
	*	91/16882	11/1991	WO				
LSC	*	92/10229	06/1992	WO				
	*	93/00951	01/1993	WO				

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**Other Documents**

Examiner Initial	No.	Author, Title, Date, Place (e.g. Journal) of Publication
LSu	*	ANDREWS, "Gelatin Capsules Revamped for New Generation of Pills," New York Times, Saturday, September 16, 1992, 19(N), 35(L), col. 5, 9 col. in.
	*	ANNEAR, "Observations on Drying Bacteria from the Frozen and from the Liquid State," Austral. J. Exp. Biol. (1958), 36:211-221.
	*	BJÖRK ET AL., "Degradable Starch Microspheres as a Nasal Delivery System for Insulin" International J. of Pharmaceutics (1988), 47:233-238.
	*	BOHNET, "Calculation and Design of Gas/Solid-Injectors," Powder Tech. (1984), pp. 302-313.
	*	BONE ET AL., "Dielectric Studies of Protein Hydration and Hydration-Induced Flexibility," J. Mol. Biol. (1985), 181:323-326.
	*	BRUNI ET AL., "Glass Transitions in Soybean Seed, Relevance to Anhydrous Biology," Plant Physiol. (1991), 96:660-663.
	*	BUDRIK ET AL., "Ejector Feeders for Pneumatic Transport Systems," Chemical & Petroleum Engineering, Sep.-Oct. 1978, 14(9-10):9-10.
	*	BURKE, "The Glassy State and Survival of Anhydrous Biological Systems," Membranes, Metabolism and Dry Organisms, Appendix D, 1986, A. Carl Leopold Editor, pp. 358-363.
	*	BYRON ET AL., "Drug Delivery Via the Respiratory Tract," J. of Aerosol Medicine (1994), 7(1):49-75
	*	CAFFREY ET AL., "Lipid-Sugar Interactions, Relevance to Anhydrous Biology," Plant Physiol. (1988), 86:754-758.
	*	CARPENTER ET AL., "Stabilization of Phosphofructokinase During Air-Drying with Sugars and Sugar/Transition Metal Mixtures," Cryobiology (1987), 24:455-464.
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	*	CARPENTER ET AL., "Modes of Stabilization of a Protein by Organic Solutes During Desiccation," Cryobiology (1988), 25:459-470.
	*	CHIEN ET AL., "Intranasal Drug Delivery for Systemic Medications," CRC Critical Reviews in Therapeutic Drug Carrier Systems (1987), 4(2):67-92.
LSu	*	CHOPIN ET AL., "Destruction de Microbacterium Lacticum, Escherichia coli et Staphylococcus Aureus au cours du schage du lait par atomisation," Can. Microbiol. (1977), 23:716-720. No translation.
<b>Examiner:</b> KSu		<b>Date Considered:</b> 12/04

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**Other Documents**

Examiner Initial	No.	Author, Title, Date, Place (e.g. Journal) of Publication
LSu	*	COLTHROPE ET AL., "The Pharmacokinetics of Pulmonary-Derived Insulin: A Comparison of Intratracheal and Aerosol Administration to the Rabbit," Pharm. Res. (1992), <u>9</u> (6):764-768.
	*	CROWE ET AL., "Stabilization of Dry Phospholipid Bilayers and Proteins by Sugars," Biochem. J. (1987), <u>242</u> :1-10.
	*	CROWE ET AL., "Are Freezing and Dehydration Similar Stress Vectors? A Comparison of Modes of Interaction of Stabilizing Solutes with Biomolecules," Cryobiology (1990), <u>27</u> :219-231.
	*	DUCHATEAU, "Bile Salts and Intranasal Drug Absorption," International J. of Pharmaceutics (1986), <u>31</u> :193-199.
	*	DOLOVICH, "Lung Dose, Distribution, and Clinical Response to Therapeutic Aerosols," Aerosol Sci. and Tech. (1993), <u>18</u> :230-240.
	*	ELLIOT ET AL., "Parental Absorption of Insulin for the Lung in Diabetic Children," Aust. Paediatr. J. (1987), <u>23</u> :293-297.
	*	FAHY, "The Relevance of Cryoprotectant 'Toxicity' to Cryobiology," Cryobiology (1986), <u>23</u> :1-13.
	*	FINNEY ET AL., "Protein Hydration and Enzyme Activity: The Role of Hydration Induced Conformation and Dynamic Changes in the Activity of Lysozyme," Comments Mol. Cell. Biophys. (1984), <u>2</u> (3-4):129-151.
	*	FLINK, Chapter 17 entitled "Structure and Structure Transitions in Dried Carbohydrate Materials," Physical Properties of Foods, 1983, M. Peleg and E. B. Bagley (Editions), pp. 473-521.
	*	FOX ET AL., "Performance of a Venturi Eductor as a Feeder in a Pneumatic Conveying System," Powder & Bulk Engineering, March 1988, pp. 33-36.
	*	FRIEDMANN, "Progress Toward Human Gene Therapy," Science June 16, 1989, <u>244</u> :1275-1281.
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	*	GENDLER ET AL., "Permethyl Analogue of the Pyrrolic Antibiotic Disctamycin A," J. Med. Chem. (1981), <u>24</u> (1):33-38.
	*	GOETZ, Editor, Chapter Climate and Weather entitled "Atmospheric Humidity and Precipitation," The New Encyclopedia Britannica (1985), <u>16</u> :476-479.
LSu	*	GOVINDA, "Aerosol Insulin Inhalation Enquiry," Indian J. Physiol. Pharmacol. (1959), <u>3</u> :161-167.
<b>Examiner:</b> Kudu		<b>Date Considered:</b> 12/04

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**Other Documents**

Examiner Initial	No.	Author, Title, Date, Place (e.g. Journal) of Publication
LSH	*	GREEN ET AL., "Phase Relations and Vitrification in Saccharide-Water Solutions and The Trehalose Anomaly," J. Phys. Chem. (1989), <u>93</u> :2880-2882.
	*	HABENER, "Parathyroid Hormone: Secretion and Metabolism In Vivo," Proc. Nat. Acad. Sci., USA, Dec. 1971, <u>68</u> (12):2986-2991.
	*	HASTINGS ET AL., Clearance of Different-Sized Proteins from the Alveolar Space in Humans and Rabbits" J. Appl. Physiol. (1992), <u>73</u> :1310-1316.
	*	HEINEMANN ET AL., "Time-Action Profile of Inhaled Insulin," Diabetic Medicine (1997), <u>14</u> :63-72.
	*	HERRINGTON, "Some Physico-Chemical Properties of Lactose: The Spontaneous Crystallization of Super-Saturated Solutions of Lactose," J. Dairy Science (1934), <u>17</u> :501-518.
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	*	HUBBARD ET AL., "Strategies for Aerosol Therapy of $\alpha_1$ -Antitrypsin Deficiency by the Aerosol Route," Lung, 1990, <u>168</u> , Supplement 1990, Proceedings of the 8 <sup>th</sup> Congress of SEP, Edited by H. Matthys, pp. 565-578.
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<b>Examiner:</b> <i>LSH</i>		<b>Date Considered:</b> <i>12/04</i>

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	<b>Filing Date:</b> 07/01/2003	<b>Group:</b> 1616

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Lsu	*	"Production of Trehalose Dried Eggs," D5, Tg Measurements, Undated, 10 pages.

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